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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,819	11/06/2000	Akira Aomatsu	5774-01-MJA	5038

7590 06/02/2005

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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,819	AOMATSU, AKIRA	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-42* is/are pending in the application.

4a) Of the above claim(s) *29 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,30 and 35-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00.

DETAILED ACTION

Note: The examiner, and the Group Art Unit location for your application in the PTO have changed. The new Group Art Unit is 1639.

Application and Claims Status

1. Applicant's amendment filed 02/21/2004 and response filed 03/08/2005 is acknowledged and entered. Claims 1-27 have been canceled. Claims 28-42 have been added.

2. Claims 22-27 were added by the amendment filed on 04/20/2003.

3. Claims 28-42 are pending.

Election/Restrictions

4. Applicant has elected the following species for the elected invention (Claims 28-42) in the reply filed on 03/08/2005:

a. A ***single specific*** species of humectant. Applicant has elected propylene glycol.

b. A ***single specific*** species of auxiliary agent. Applicant has elected hydroxypropylcellulose.

c. A ***single specific*** species of neutral amino acid. Applicant has elected glycine.

2. Applicant's election with traverse of the species election in the reply filed on 03/08/2005 is acknowledged.

The traversal is on the ground that there is no burden to search and examine all species.

This is not found persuasive because as indicated in the Office action mailed on 02/08/2005, the species are distinct, each from the other, because each species have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Applicant has not shown why these species are not distinct.

Thus, the requirement is still deemed proper.

3. Claims 29, and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/08/2005.

5. Claims 28, 30, and 35-42 are treated on the merit in this Office Action.

Priority

6. It is noted that this instant application is a 371 of PCT/US99/10,186 filed 05/10/1999, which claims benefit to a foreign application, which is JAPAN 133112/98 filed 05/15/1998 under 35 U.S.C 119(a)-(d). Thus, the instant application is granted the benefit of priority for PCT/US99/10,186 filed 05/10/1999, and foreign priority to JAPAN 133112/98 filed 05/15/1998.

New Rejection(s) – Necessitated by Amendment

7. Claims 28, 30, and 35-42 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28, 36, 40, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Jao et al. (US Patent 5,660,861).

Jao et al. disclose a dosage form for delivering an antiepileptic drug and the method of making the dosage form (see e.g. Abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5; col. 10, line 65 thru col. 13, line 44). The dosage form comprises the form of a tablet or capsule (see e.g. col. 5, lines 14-26; col. 15, lines 34-53; fig. 1). The dosage form comprises an antiepileptic drug such as gabapentin (refers to the instant claimed 4-amino-3-substituted butanoic acid derivative, i.e. gabapentin) (see e.g. col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27), osmagent such as sorbitol (refers to the instant claimed humectant) (see e.g. col. 7, lines 42-52), and exterior coating such as hydroxypropylcellulose (refers to instant claimed auxiliary agent, and the elected species of hydroxypropylcellulose) (see e.g. col. 9, lines 8-25; col. 17, lines 23-52). The method comprises mixing the drug with the composition forming ingredients (see e.g. col. 12, line 63 thru col. 13, line 24). Thus, the dosage form and method of making the dosage form of Jao et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 28, 30, 35-37, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao et al. (US Patent 5,660,861) and Giacin et al. (US Patent 5,302,373).

Jao et al. disclose a dosage form for delivering an antiepileptic drug and the method of making the dosage form (see e.g. Abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5; col. 10, line 65 thru col. 13, line 44). The dosage form comprises the form of a tablet or capsule (see e.g. col. 5, lines 14-26; col. 15, lines 34-53; fig. 1). The dosage form comprises an antiepileptic drug such as gabapentin (refers to the instant claimed 4-amino-3-substituted butanoic acid derivative, i.e. gabapentin) (see e.g. col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27), osmagent such as sorbitol (refers to the instant claimed humectant) (see e.g. col. 7, lines 42-52), and exterior coating such as hydroxypropylcellulose (refers to instant claimed auxiliary agent, and the elected species of hydroxypropylcellulose) (see e.g. col. 9, lines 8-25; col. 17, lines 23-52). The method comprises mixing the drug with the composition forming ingredients (see e.g. col. 12, line 63 thru col. 13, line 24).

Additionally, The features of remaining dependent claims are either specifically described by the reference, or constitute obvious variations in parameters which are routinely modified in the art (e.g. the percentage of each compounds in the composition), and which have not been described as critical to the practice of the invention.

The composition of Jao et al. differs from the presently claimed invention by failing to include a type of humectant that is propylene glycol.

Giacin et al. disclose a mouthwash composition (see e.g. Abstract; col. 1, line 60 thru col. 2, line 2). The composition comprises a humectant such as propylene glycol, and sorbitol (see e.g. col. 2, lines 29-33). The humectant adds body and a pleasant mouth feel (see e.g. col. 2, lines 29-33).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a type of humectant that is propylene glycol as taught by Giacin et al. in the composition of Jao et al. One of ordinary skill in the art would have been motivated to include a type of humectant that is propylene glycol in the composition of Jao et al. for the advantage of providing a humectant that adds body and a pleasant mouth feel (Giacin: col. 2, lines 29-33) since both Jao et al. and Giacin et al. disclose a pharmaceutical excipient such as sorbitol (Jao: col. 7, lines 42-52; Giacin: col. 2, lines 29-33). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Jao et al. and Giacin et al. because Giacin et al. disclose that sorbitol, propylene glycol, and glycerol are functionally equivalent humectant (Giacin: col. 2, lines 29-33).

12. Claims 28, and 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao et al. (US Patent 5,660,861) and Robson et al. (US Patent 4,126,684).

Jao et al. disclose a dosage form for delivering an antiepileptic drug and the method of making the dosage form (see e.g. Abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5;

col. 10, line 65 thru col. 13, line 44). The dosage form comprises the form of a tablet or capsule (see e.g. col. 5, lines 14-26; col. 15, lines 34-53; fig. 1). The dosage form comprises an antiepileptic drug such as gabapentin (refers to the instant claimed 4-amino-3-substituted butanoic acid derivative, i.e. gabapentin) (see e.g. col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27), osmagent such as sorbitol (refers to the instant claimed humectant) (see e.g. col. 7, lines 42-52), and exterior coating such as hydroxypropylcellulose (refers to instant claimed auxiliary agent, and the elected species of hydroxypropylcellulose) (see e.g. col. 9, lines 8-25; col. 17, lines 23-52). The method comprises mixing the drug with the composition forming ingredients (see e.g. col. 12, line 63 thru col. 13, line 24).

Additionally, The features of remaining dependent claims are either specifically described by the reference, or constitute obvious variations in parameters which are routinely modified in the art (e.g. the percentage of each compounds in the composition), and which have not been described as critical to the practice of the invention.

The composition of Jao et al. differs from the presently claimed invention by failing to include a neutral amino acid such as glycine.

Robson et al. disclose a pharmaceutical composition and the method of use (see e.g. Abstract; col. 1, lines 36-57). The composition comprises a drug such as 4-amino-3-p-halophynel-butyric acid, and a pharmaceutical excipient such as sorbitol and glycine (see e.g. col. 2, lines 5-8, and 37-52; col. 3, lines 54-59).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a neutral amino acid such as glycine as taught by Robson et al. in the composition of Jao et al. One of ordinary skill in the art would have been motivated to

include a neutral amino acid such as glycine in the composition of Jao et al. for the advantage of providing a delivery system that would deliver the drug formulation in continuous-release dose for predictable and improve therapy (Jao: col. 3, lines 20-25) since both Jao et al. and Robson et al. disclose a pharmaceutical excipient such as sorbitol and a drug that is 4-amino-3-substituted butanoic acid derivative (Jao: col. 6, lines 52-67, and col. 7, lines 42-52; Robson: col. 2, lines 5-8, and col. 3, lines 54-59). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Jao et al. and Robson et al. because Robson et al. that sorbitol, and glycine are functionally equivalent.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 28, 36, and 38-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-27, and 30-32 of copending Application No. 09/674,815 in view of Jao et al. (US Patent 5,660,861).

The copending Application No. 09/674,815 claimed a composition comprising an α amino acid such as glycine, an auxiliary agent, and 4-amino-3-substituted butanoic acid derivative such as gabapentin.

The composition of copending Application No. 09/674,815 differs from the presently claimed invention by failing to include a humectant.

Jao et al. disclose a dosage form for delivering an antiepileptic drug and the method of making the dosage form (see e.g. Abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5; col. 10, line 65 thru col. 13, line 44). The dosage form comprises the form of a tablet or capsule (see e.g. col. 5, lines 14-26; col. 15, lines 34-53; fig. 1). The dosage form comprises an antiepileptic drug such as gabapentin (refers to the instant claimed 4-amino-3-substituted butanoic acid derivative, i.e. gabapentin) (see e.g. col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27), osmagent such as sorbitol (refers to the instant claimed humectant) (see e.g. col. 7, lines 42-52), and exterior coating such as hydroxypropylcellulose (refers to instant claimed auxiliary agent, and the elected species of hydroxypropylcellulose) (see e.g. col. 9, lines 8-25; col. 17, lines 23-52).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a humectant as taught by Jao et al. in the composition of copending Application No. 09/674,815. One of ordinary skill in the art would have been motivated to include a humectant in the composition of copending Application No. 09/674,815 for the advantage of providing a dosage form that delivers an antiepileptic drug formulation orally to a patient (Jao: col. 3, lines 26-28) since both the copending Application No. 09/674,815 and Jao et al. disclose the drug is gabapentin of the pharmaceutical composition (09/674,815:

claims 25, and 31; Jao: col. 6, lines 52-67). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of copending Application No. 09/674,815, and Jao et al. because Jao et al. disclose that they're several different method for manufacturing the pharmaceutical preparation (Jao: col. 10, line 65 thru col. 13, line 44) such that the type of pharmaceutical excipient use would be a choice of experimental design and is considered within the purview of the cited prior art.

This is a provisional obviousness-type double patenting rejection.

Withdrawn Objection(s) and /or Rejection(s)

15. The rejections of claims 6, 13, 23, and 26 under 35 USC 112, second paragraph, as being indefinite has been withdrawn in light of applicant's cancellation of claims 1-27.

16. The rejection of claims 1, 10-12, 14, 22, and 25 under 35 USC 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Augart et al (US' 6,054,482) in view of US5302373, Telev (1982, abstract), US5618342 and/or BE645388 has been withdrawn in light of applicant's cancellation of claims 1-37. Applicant's arguments are considered but are moot in view of the new grounds of rejection.

17. The rejection of claims 1, 2, 7-14, 22, and 25 under 35 USC 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cherukuri et al. (EP 0458751) has been withdrawn in light of applicant's cancellation of claims 1-37. Applicant's arguments are considered but are moot in view of the new grounds of rejection.

18. The rejection of claims 1, 7-17, and 20-21 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Robson et al. (US 4,126,684) has been withdrawn in light of applicant's cancellation of claims 1-37. Applicant's arguments are considered but are moot in view of the new grounds of rejection.

19. The rejection of claims 1-7, 10-15, and 20-27 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US 5,025,035) has been withdrawn in light of applicant's cancellation of claims 1-37. Applicant's arguments are considered but are moot in view of the new grounds of rejection.

Response to Arguments

20. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
May 31, 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER